K061683

510(k) Summary

JUL 21 2006

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
317-521-3723

Contact Person: Theresa M. Ambrose

Date Prepared: May 5, 2006

Device Name

Proprietary name: Tina-Quant ® Myoglobin Gen.2 test system; C.f.a.s. (Calibrator for automated systems) Myoglobin

Common name: Myoglobin Test system, calibrator

Classification name: Myoglobin immunological test system; Calibrator, secondary

Predicate devices

The Tina-Quant® Myoglobin Gen.2 test system is substantially equivalent to the currently marketed Tina-Quant ® Myoglobin Test System cleared under K972513.

Device Description

The Tina-Quant® Gen.2 Test System is an immunoturbidimetric assay for the quantitative in vitro determination of myoglobin in human serum and plasma on Roche automated clinical chemistry analyzers. In this immunoturbidimetric method, latex-bound anti-myoglobin antibodies react with antigen in the sample to form an antigen/antibody complex which after agglutination can be determined turbidimetrically. The calibrator is C.f.a.s. Myoglobin and the recommended control material is the Myoglobin Control Set.

510(k) Summary, **Continued**

Intended use

The Tina-Quant® Gen.2 Test System is an immunoturbidimetric assay for the quantitative in vitro determination of myoglobin in human serum and plasma on Roche automated clinical chemistry analyzers.
C.f.a.s. (calibrator for automated systems) Myoglobin is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed values sheet.

Comparison to predicate device

The below table compares the Tina-Quant ® Myoglobin Gen.2 Test System with the predicate device, Tina-Quant ® Myoglobin Test System (K972513)

Substantial equivalence: comparison table

Characteristic	**Tina-Quant ® Myoglobin Gen.2 Test System**	**Predicate device Tina-Quant ® Myoglobin Test System (K972513)**
Intended Use	for the quantitative in vitro determination of myoglobin in human serum and plasma on Roche automated clinical chemistry analyzers	for the quantitative in vitro determination of myoglobin in human serum and plasma using automated clinical chemistry analyzers
Indications for use	Same	Measurement of myoglobin aids in the rapid diagnosis of heart and renal disease.
Assay principle	Same	Immunoturbidimetry
Instrument	Will be applied to Hitachi family (including cobas c6000 series) and Integra family analzyers	Hitachi family of analyzers
Reagent Stability	• Unopened kit: up to the stated expiration date at 2-8 °C • On board the analyzer: 12 weeks opened and refrigerated	• Unopened kit: up to the stated expiration date at 2-8 °C • On board the analyzer : 28 days at 2-8 °C
Reagent format	liquid	liquid
Reagent composition	R1: same except for minor variations in stabilizers R2: Latex particles, loaded with anti-human myoglobin antibody(rabbit), 0.1% (w/v) glycine buffer 170 mmol/L; NaCl 100 mmol/L, preservative Same antibody but different procedure for coating latex with antibody.	R1: Glycine buffer:170 mmol/L; NaCl 100 mmol/L, EDTA 50 mmol/.L, preservative R2: Latex particles, loaded with anti-human myoglobin antibody(rabbit), 0.12% (w/v) glycine buffer 170 mmol/L; NaCl 100 mmol/L, preservative

510(k) Summary, Continued, Continued

Predicate devices (continued)

Characteristic	Tina-Quant ® Myoglobin Gen.2 Test System	Predicate device Tina-Quant ® Myoglobin Test System (K972513)
Sample type	Same	Serum or plasma with Li, Na heparin; or EDTA
Calibrator	C.f.a.s Myoglobin	In-kit calibrator
Calibrator composition	Same	Human myoglobin in a bovine serum albumin matrix
Calibrator configuration	Provided separately from kit.	Provided with kit
Calibrator levels	One level	Four levels provided
Traceability/ standardization	Standardized against a selected manufacturer's measurement procedure (immunological method). Results are corrected by + 8 ug/L to maintain traceability. Performance validated using this correction.	NIBSC reagents
Controls	same	Myoglobin Control Set
Measuring range	Hitachi 902:30-580 ug/L Other Hitachi: 20-580 ug/L, 20-5800 ug/L with extended measuring range	3-560 ug/L 3-4500 ng/ mL with extended measuring range
Lower Detection Limit	Hitachi 902: < 20 ug/L Other Hitachi: < 15ug/L	3 ug/L
Within-run precision (%CV)	1.1% at 36.3 ug/L 0.7% at 60.9 ug/L 0.3% at 252 ug/L 0.7% at 129 ug/L	2.6% at 32.3 ug/L 0.9% at 71.3 ug/L 0.3% at 471.5 ug/L

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510(k) Summary, Continued, Continued

Predicate devices (continued)

Characteristic	Tina-Quant ® Myoglobin Gen.2 Test System	Predicate device Tina-Quant ® Myoglobin Test System (K972513)
Between-run precision (%CV)	2.0% at 63.1 ug/L 1.4% at 240 ug/L 1.8% at 62.4 ug/L 1.8% at 265 ug/L	3.3% at 71.4 ug/L 1.7% at 459.1 ug/L
Limitations: interferences	No significant interference up to • I index of 60 (Conjugated and unconjugated bilirubin up to 60 mg/dL) • H index of 500 (Hemoglobin up to 500 mg/dL) • L index of 500 (Intralipid) • Rheumatoid factors up to 100 IU/mL No interference from 18 commonly used pharmaceuticals In rare cases gammopathy, in particular type IgM, may cause unreliable results. A high-dose hook effect may occur at myoglobin concentrations >10000 ug/L The results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.	No significant interference from • Conjugated and unconjugated bilirubin up to 60 mg/dL • Hemolysis up to 0.5 g/dL hemoglobin • Lipemia up to 1500 mg/dL • Rheumatoid factors up to 100 IU/mL
Expected values	Men: 23-72 ug/L Women: 19-51 ug/L	Men: 16-76 ug/L Women: 7-64 ug/L
Method comparison	y = Tina-Quant ® Myoglobin Gen.2 x = Tina-Quant Myoglobin Passing-Bablok results: y=1.016x + 4.3 T = 0.961; r = 0.992	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUL 21 2006

Re: k061683
Trade/Device Name: Tina-Quant® Myoglobin Gen.2 Test System
C.f.a.s. (Calibrator for automated systems) Myoglobin
Regulation Number: 21 CFR§866.5680
Regulation Name: Myoglobin immunological test system
Regulatory Class: Class II
Product Code: DDR, JIT
Dated: June 15, 2006
Received: June 15, 2006

Dear Dr. Bush;

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Tina-Quant ® Myoglobin Gen.2 Test System**

Indications For Use:

The Tina-Quant ® Myoglobin Gen.2 Test System is an immunoturbidimetric assay for the quantitative in vitro determination of myoglobin in human serum and plasma on Roche automated clinical chemistry analyzers. Measurement of myoglobin aids in the rapid diagnosis of heart and renal disease.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

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...aluation and Safety

K001683

Indications for Use

510(k) Number (if known):

Device Name: **C.f.a.s. (Calibrator for automated systems) Myoglobin**

Indications For Use:

C.f.a.s. (Calibrator for automated systems) Myoglobin is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson

Division Sign-Off

Page 2 of 2

Office of In Vitro Diagnostic Device
Evaluation and Safety

K061683